UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,657	12/22/2004	Cinderella Christina Gerhardt	F7649(V)	9203

201 7590 04/07/2008

UNILEVER INTELLECTUAL PROPERTY GROUP
700 SYLVAN AVENUE,
BLDG C2 SOUTH
ENGLEWOOD CLIFFS, NJ 07632-3100

EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
04/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,657	GERHARDT ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-9,12 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-9,12 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20080226;20080303*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 3, 2008 has been entered.

2. Applicant is advised that should claim 3 be found allowable, claim 12 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 3 and 12 are identical in scope.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-5, 7-9, 12, and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 and 15-17 of copending Application No. 10/539,434. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '434 application anticipate instant claims 1, 3, 5, 7-9, and 12. Because the same active agent is being administered to the same subject according to the same method steps, inherently obesity and/or being overweight will be prevented in the claimed method of the '434 application to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the claimed method of the '434 application and the instant claimed method to shift the burden to Applicants to provide evidence that their claimed method is unobviously different than the claimed method of the '434 application. Further, the '434 application claims its method as part of a dietary plan or a weight management program (see claim 7 of the '434 application). With respect to instant claim 4, while the '434 application claims the use of a mixture of hydrolysates of β-lactoglobulin and α-lactalbumin, the '434 application does not claim a weight ratio for these two components. It would have been obvious to one of ordinary skill in the art to determine all operable and optimal component ratios for the hydrolysates of β-lactoglobulin and α-lactalbumin administered in the claimed method of the '434 application, because component ratio is an art-recognized result-effective variable which is routinely determined and optimized in the food and drug arts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1, 3-5, 8, 9, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Davis et al (U.S. Patent No. 6,630,320). Davis et al teach orally administering to mammals a composition comprising hydrolyzed whey proteins. The composition comprises whey proteins, including β-lactoglobulin and α-lactalbumin in ratios embraced within the range recited in instant claim 4, subjected to hydrolysis with trypsin to a degree of hydrolysis ranging from 4.5% to 17%. The compositions in powder form can be dissolved in PBS for oral administration. See, e.g., the Abstract; column 2, lines 15-17 and 25-37; column 5, lines 51-55; column 8, lines 9-19; and claims 1 and 3-5. In view of the similarity in chemical composition, method of making the chemical composition, and method of administering the chemical composition, between Davis et al and Applicants' claims, inherently administration of the compositions of Davis et al will result in induced cellular release of glucagon-like peptides and cholecystokinins and will result in prevention of obesity or being overweight to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the method of Davis et al and Applicants' claimed method to shift the burden to Applicants to provide evidence that Applicants' claimed method is unobviously different than the method of Davis et al. Note that a prior art reference need not recognize or suggest Applicants' intended results in order to anticipate Applicants' claimed methods on the basis of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1391 (BPAI 1993). See also In re Cruciferous Sprouts Litigation, 64 USPQ2d 1202 (Fed. Cir. 2002) and MPEP 2112 and 2112.01.

6. Claims 1, 3, 7, 8, 12, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by the Aoyama et al article (Biosci. Biotechnol. Biochem., Vol. 64, pages 2594-2600). The Aoyama et al article teaches treating obese mice by administering a whey protein isolate

hydrolysate (WPI-H) as part of an energy-restricted low fat and high protein diet. The WPI-H has an average molecular weight of 4600. See, e.g., the Abstract; page 2595; and Table 3. Because whey protein inherently comprises a mixture of β-lactoglobulin and α-lactalbumin, inherently the WPI-H of the Aoyama et al article will comprise a mixture of hydrolysates of the β-lactoglobulin and α-lactalbumin. In view of the similarity in chemical composition and method of administering the chemical composition, between the Aoyama et al article and Applicants' claims, inherently administration of the composition of the Aoyama et al article will result in induced cellular release of glucagon-like peptides and cholecystokinins to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the method of the Aoyama et al article and Applicants' claimed method to shift the burden to Applicants to provide evidence that Applicants' claimed method is unobviously different than the method of the Aoyama et al article. Note that a prior art reference need not recognize or suggest Applicants' intended results in order to anticipate Applicants' claimed methods on the basis of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1391 (BPAI 1993). See also In re Cruciferous Sprouts Litigation, 64 USPQ2d 1202 (Fed. Cir. 2002) and MPEP 2112 and 2112.01.

7. Claim 5 is rejected under 35 U.S.C. 102(b) as being by the Aoyama et al article (Biosci. Biotechnol. Biochem., Vol. 64, pages 2594-2600) as applied against claims 1, 3, 7, 8, 12, and 19 above, and further in view of Garcia-Rodenas et al (U.S. Patent Application Publication 2004/0248768). The Aoyama et al article teaches an average molecular weight for the WPI-H of 4600, but does not teach a degree of hydrolysis for this WPI-H. Garcia-Rodenas et al teach that for a whey protein hydrolysate, a degree of hydrolysis of 30% means that the major part of the protein matter is present in the form of dipeptides. See paragraph [0038]. In view of the average

molecular weight of the WPI-H of the Aoyama et al article, the major part of the protein matter will be present in the form of peptides significantly larger than dipeptides (a peptide of molecular weight 4600 comprises about 40-46 amino acids), and therefore will have a degree of hydrolysis significantly less than the 30% value taught by Garcia-Rodenas et al. In view of the relationship between degree of hydrolysis and molecular weight taught by Garcia-Rodenas et al, the WPI-H of the Aoyama et al article inherently will have a degree of hydrolysis in the range of from 1 to 20%. Sufficient evidence of similarity is deemed to be present between the WPI-H of the Aoyama et al article and the whey protein hydrolysate recited in instant claim 5 to shift the burden to Applicants to provide evidence that the claimed invention, and in particular the whey protein hydrolysate of instant claim 5, is unobviously different than the WPI-H of the Aoyama et al article.

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being obvious over the Aoyama et al article (Biosci. Biotechnol. Biochem., Vol. 64, pages 2594-2600) as applied against claims 1, 3, 7, 8, 12, and 19 above, and further in view of Baker et al (U.S. Patent Application Publication 2002/0061539). The Aoyama et al article teaches WPI-H, but does not teach a weight ratio for hydrolysates of the β-lactoglobulin and α-lactalbumin present within the WPI-H. Baker et al teach that WPI typically comprises β-lactoglobulin and α-lactalbumin in a weight ratio of 5:1. See paragraph [0034]. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use a typical WPI as the source of the WPI-H used in the method of Aoyama et al article, and therefore it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use a WPI comprising β-lactoglobulin and α-lactalbumin in a weight ratio of 5:1 which Baker et al teach is typical of WPI.

9. Claim 9 is rejected under 35 U.S.C. 103(a) as being obvious over the Aoyama et al article (Biosci. Biotechnol. Biochem., Vol. 64, pages 2594-2600). Application of the Aoyama et al article is the same as in the above rejection of claims 1, 3, 7, 8, 12, and 19. The Aoyama et al article does not teach administering the WPI-H in one of the particular forms recited in instant claim 9. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to administer the WPI-H of the Aoyama et al article in any physical form, including those recited in instant claim 9, because the physical forms recited in instant claim 9 are well-known and convenient forms for foods, and because the physical form of the WPI-H being administered in the method of the Aoyama et al article would not have been expected materially to affect the biochemical effects which the WPI-H has upon digestion.

10. Claims 1, 3, 7-9, 12, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by the Demling et al article (Ann. Nutr. Metab., Vol. 44, pages 21-29). The Demling et al article teaches treating overweight and obese human beings by administered a whey protein hydrolysate in powder form dissolved in a liquid. Administration of the whey protein hydrolysate as part of a diet and exercise program results in weight loss. See, e.g., the Abstract; page 23, column 1, last paragraph; page 25, column 2, last paragraph; and page 26, column 2, first full paragraph. Because whey protein inherently comprises a mixture of β-lactoglobulin and α-lactalbumin, inherently the whey protein hydrolysate of the Demling et al article will comprise a mixture of hydrolysates of the β-lactoglobulin and α-lactalbumin. In view of the similarity in chemical composition, method of administering the chemical composition, and intended use of the chemical composition between the Demling et al article and Applicants' claims, inherently administration of the composition of the Demling et al article will result in induced cellular

release of glucagon-like peptides and cholecystokinins to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the method of the Demling et al article and Applicants' claimed method to shift the burden to Applicants to provide evidence that Applicants' claimed method is unobviously different than the method of the Demling et al article. Note that a prior art reference need not recognize or suggest Applicants' intended results in order to anticipate Applicants' claimed methods on the basis of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1391 (BPAI 1993). See also In re Cruciferous Sprouts Litigation, 64 USPQ2d 1202 (Fed. Cir. 2002) and MPEP 2112 and 2112.01.

11. Claim 4 is rejected under 35 U.S.C. 103(a) as being obvious over the Demling et al article (Ann. Nutr. Metab., Vol. 44, pages 21-29) as applied against claims 1, 3, 7-9, 12, and 19 above, and further in view of Baker et al (U.S. Patent Application Publication 2002/0061539). The Demling et al article teaches a whey protein hydrolysate, but does not teach a weight ratio for hydrolysates of the β-lactoglobulin and α-lactalbumin present within the whey protein hydrolysate. Baker et al teach that WPI typically comprises β-lactoglobulin and α-lactalbumin in a weight ratio of 5:1. See paragraph [0034]. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use a typical WPI as the source of the whey protein for the hydrolysate used in the method of the Demling et al article, and therefore it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use a whey protein isolate comprising β-lactoglobulin and α-lactalbumin in a weight ratio of 5:1 which Baker et al teach is typical of WPI.

12. Claim 5 is rejected under 35 U.S.C. 103(a) as being obvious over the Demling et al article (Ann. Nutr. Metab., Vol. 44, pages 21-29). Application of the Demling et al article is the

same as in the above rejection of claims 1, 3, 7-9, 12, and 19. The Demling et al article teaches administering a whey protein hydrolysate, but does not teach a degree of hydrolysis for the whey protein hydrolysate. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal degrees of hydrolysis for the whey protein hydrolysate of the Demling et al article, because degree of hydrolysis is an art-recognized result-effective variable which is routinely determined and optimized for protein hydrolysates.

13. Applicant's arguments filed March 3, 2008 have been fully considered but they are not persuasive.

The anticipation rejection over Davis et al (U.S. Patent No. 6,630,320) is maintained. Davis et al teach a method in which the same active agents are administered to the same subjects according to the same method steps recited in Applicants' claims. Prima facie, it can be concluded that Davis et al will achieve the same results claimed by Applicants, i.e. induced cellular release of glucagon-like peptides and cholecystokinins and prevention of obesity or being overweight. Identity in methods steps, active agents, and subjects is sufficient to support a conclusion that the same results will inevitably occur.

The obviousness rejection over Davis et al (U.S. Patent No. 6,630,320) in view of Katz et al (U.S. Patent Application Publication 2002/0081315) and Ward et al (U.S. Patent Application Publication 2003/0165574) is withdrawn in favor of the new prior art rejections set forth above.

14. The WO Patent Application 2004/069265 is cited as art of interest; however, instant claims 1, 3-5, 7-9, 12, and 19 are deemed to be entitled under 35 U.S.C. 119(a)-(d) to the benefit

of the filing date of the EPO foreign priority document, and accordingly the WO Patent Application '265 is not available as prior art under 35 U.S.C. 102 against the instant claims.

The Hall et al abstract (Proc. Nutr. Soc., Vol. 60, pages 227A) is cited as art of interest; however, Applicants' claims have been amended to require the administration of a whey protein hydrolysate, which the Hall et al abstract does not teach or suggest.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
April 7, 2008